

# The Acquis in the field of Legal Metrology

- **✓** Units of Measurement
- **✓** Measuring Instruments
- ✓ Pre-packaging



The main challenge is how to create ...

Starting from a great variety of countries, technical regulations, cultures, industrial standards & administrative infrastructures ...

... one single market



- ✓ one common technical environment
- ✓ one common legislative framework
- ✓ one coordinated enforcement policy
- ✓ high competitiveness
- ✓ fast innovation



#### Implementation:

- ✓ Harmonisation (NLF)
- ✓ Guidance
- ✓ Standardisation
- ✓ Administrative Cooperation



# Legal Metrology

#### Legal metrological control is:

- ✓ One of the oldest regulated areas in society.
- ✓ Highly complex and technical.
- ✓ Unexpected high political profile, with large and sometimes agitated press coverage.



#### Units of measurement

#### Directive 80/181/EEC on units of measurement:

- ✓ Economic, public health, public safety or administrative purposes, with exception of international transport
- ✓ SI-units mentioned in Chapter 1 are mandatory
- ✓ Supplementary indications allowed but not defined (fl. oz)
- ✓ Exemptions: UK & IRL pint, mile, troy ounce
- ✓ Last update: Directive 2009/3/EC
- ✓ Recast after comitology is updated in Directive 2009/34/EC
- <a href="http://ec.europa.eu/enterprise/sectors/legal-metrology-and-prepack/unitmeas/index\_en.htm">http://ec.europa.eu/enterprise/sectors/legal-metrology-and-prepack/unitmeas/index\_en.htm</a>



# Measuring Instruments (1)

Two series of regulation, fundamentally different in nature:

- 1. Old Approach harmonisation by Directive 71/316/EEC on common provisions, combined with 18 specific directives, all of which have been or will be repealed by 2015 at the latest.
- 2. New Approach harmonisation by
- Directive 2004/22/EC on measuring instruments (MID)
- Directive 2009/23/EC on non-automatic weighing instruments (NAWI)



- Old Approach harmonisation:
  - ✓ Directive 2009/34/EC recasts Directive 71/316/EEC
  - ✓ Directive 2004/22/EC (MID) repeals 10.5 directives from 2006
  - 10 years transition for old Type Approvals until 29 October 2016
  - Directive 75/33 repealed for clean water, the rest of it in 2011/17
  - ✓ Directive 2011/17/EU repeals 7.5 Directives (=8 incl. Dir 75/33):
    - Directive 71/349 (ship tanks) in 2011, transition until 2021
    - Other 7 Directives in 2015, transition until 2025
  - ✓ Directive 2009/34/EC is "empty" except for:
    - e-marking and  $\ni$  (= reversed epsilon) marking in Prepackages
    - Committee only for use under Units of Measurement
      No need to fully transpose, if transition, marks and committee are included



# Measuring Instruments (2)

#### New Approach harmonisation

- Measuring Instruments (MID)
- Non automatic weighing instruments (NAWI)
- ✓ Manufacturer always responsible
- ✓ Essential requirements
- ✓ Choice of conformity assessment procedure and notified body
- ✓ Open to innovation and (international) standards
- ✓ New Legal Framework package



# **New Legislative Framework**

- July 2008:
  - Regulation 765/2008: common accreditation and market surveillance framework
  - ➤ Decision 768/2008: consolidates, completes and modernises basic New Approach concepts – Model for future legislation harmonising product-related requirements

Official Journal of the EU, L218, 13.08.08



# New Legislative Framework Regulation & Decision (1)

#### REGULATION

Accreditation

Market surveillance

- internal
- imported products
   general principles

Financing elements
Applicable from 1 Jan 2010
Lex Specialis sectorals /
General Product Safety
Directive

#### DECISION

- Definitions / obligations
- Notified Bodies (criteria / process / accreditation)
- Conformity assessment procedures
- Safeguard mechanisms (& market surveillance)
- **(E** marking
- Basis for future legislation



# New Legislative Framework Regulation & Decision (2)

- REGULATION
- Covers elements not included in sectoral legislation
- Complementary to sectoral legislation
- Applicable from 1 January 2010
- Rights and obligations for Member States and individuals

**DECISION** 

Covers elements already included in legislation
Sui Generis Decision

 No direct effects for Member States or individuals

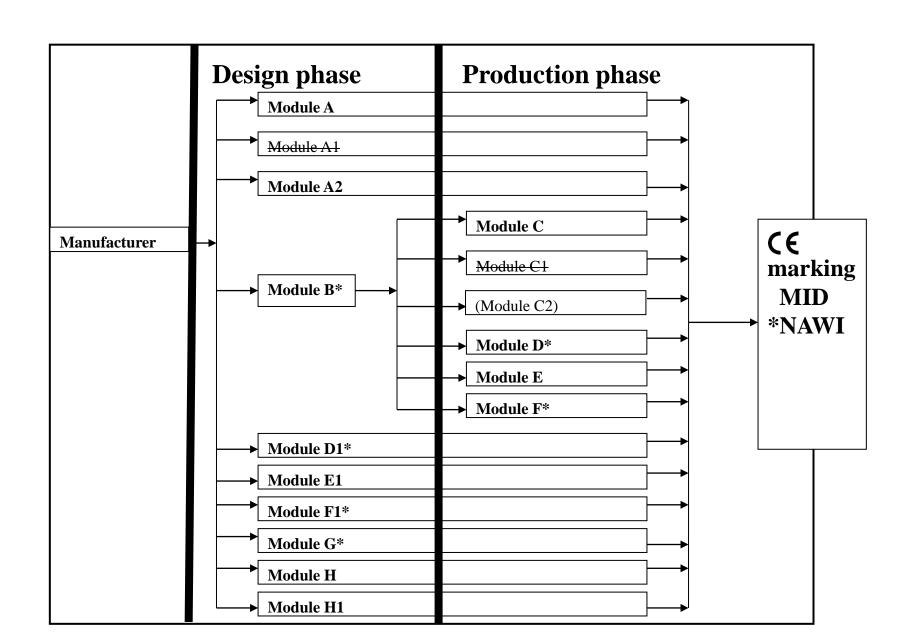
Better Regulation tool: model Articles

"toolbox"



#### The basic Modules (the ISO CASCO toolbox)

- 8 basic modules (with 13 variants)
- Range of options given to manufacturers set in individual Directives
- From a regulator's perspective, all procedures are deemed to lead to equivalent results in terms of product / system conformity





#### NLF recasts of NAWI and MID

- Official Journal <u>L 096</u> of 29 March 2014:
- NAWI = Directive 2014/31/EU, p 109-150
- MID = Directive 2014/32/EU, p 151-252
- entered into force on 18 April 2014
- Member States to transpose by 19 April 2016,
- when existing MID and NAWI are repealed



# Measuring Instruments (3)

Measuring Instruments Directive 2004/22/EC (MID) features:

"Optionality": whether or not there is legal metrological control is a Member State's decision (option) but, where legal metrological control is required, only CE marked instruments can be used (total)

"Normative Documents": Commission through Comitology can designate (parts of) OIML Documents that provide presumption of conformity to essential requirements (procedure differs from ENs, effect is the same)



# Measuring Instruments (4)

Non-automatic Weighing Instruments Directive 2009/23/EC (NAWI) features:

"Two stages": putting into use can be controlled by another notified body than the one controlling manufacturing (both NBs chosen by manufacturer), so there may be 2 notified body numbers on the instrument once installed.

"Periodic verification": Member States obliged to ensure that instruments continue to perform in conformity with the Directive.

No "normative documents", "optionality" or "comitology" (as MID) N.B. Directive 2009/23/EC recasts Directive 90/384/EEC



# Pre-packaging (1)

Metrological requirements: Directive 76/211/EEC

- ✓ Product coverage: Liquids and non-liquids
- ✓ Optional Old Approach, so packer's choice to use it
- ✓ e-mark defined in Directive 2009/34/EC
- ✓ Test procedure by authority defined in Annex II
- ✓ Evaluation in 2005 guidance needed
- ✓ e.g. drained weight & imports

http://ec.europa.eu/enterprise/sectors/legal-metrology-and-prepack/prepacked-products/index\_en.htm



# Pre-packaging (2)

Nominal quantities (pack sizes): Directive 2007/45/EC

- ✓ Mandatory for all packs
- ✓ i.e. not limited to Directive 76/211!
- ✓ Wine & spirit drinks only allowed in fixed EU sizes
- ✓ No national sizes in other sectors allowed!
- ✓ Definitions for multipacks etc.
- ✓ Aerosols exempted from weight indications!
- http://ec.europa.eu/enterprise/sectors/legal-metrology-and-prepack/documents/pack-sizes/index\_en.htm



# Pre-packaging (3)

Bottles used as measuring containers: Directive 75/107/EEC

- ✓ Very much used in glass bottles
- ✓ Notably wine, spirit drinks and milk
- ✓ Optional Old Approach, so manufacturer's choice to use it
- ✓ Test procedure by authority defined in Annex II
- ✓ ∋ (= reversed epsilon) marking defined in Directive 2009/34/EC
- <a href="http://ec.europa.eu/enterprise/sectors/legal-metrology-and-prepack/prepacked-products/index">http://ec.europa.eu/enterprise/sectors/legal-metrology-and-prepack/prepacked-products/index</a> en.htm



### Transposition

- One on one & minimise mixes
- Correlation tables are very helpful to all

Article by article in order of national law in 4 columns:

Directive text / national transposition /

national comment / Commission services comment

- Check your status with your hierarchy!
- Get rid of conflicting national rules:
   e.g. pump resets to zero before transaction is finalised
- Info: ENTR-METROLOGY@ec.europa.eu